Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

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Registration Decision

Pyriproxyfen

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Registration Decision for Pyriproxyfen

Health Canada's *Pest Management Regulatory Agency* (PMRA), under the authority of the *Pest Control Products Act*, is granting full registration for the sale and use of active ingredient pyriproxyfen and the end-use product Distance to control whiteflies (silver leaf whitefly, sweet potato whitefly and greenhouse whitefly) on greenhouse ornamentals and greenhouse vegetables (tomato, cucumber and pepper).

Current scientific data from the registrant, scientific reports and information from other regulatory agencies were evaluated to determine if, under the proposed conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1]: *Proposed Registration Decision—Pyriproxyfen* (PRDD2006-04). This Registration Decision[2] describes this stage of the PMRA's regulatory process for Pyriproxyfen and summarizes the Agency's decision and the reasons for it. The Agency received no comments concerning PRDD2006-04. This decision is consistent with the proposed registration decision as stated in *Proposed Registration Decision—Pyriproxyfen* (PRDD2006-04).

For more details on the information presented in this Registration Decision, please refer to PRDD2006-04 *Proposed Registration Decision—Pyriproxyfen* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration[3]. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2 (2) of the *Pest Control Products Act* 2002

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act* 2002: "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's a) efficacy; b) effect on host organisms in connection with which it is intended to be used; and c) health, safety and environmental benefits and social and economic impact".

To reach its decision, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g., children) and organisms in the environment (e.g., those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What is Pyriproxyfen?

Pyriproxyfen is an insecticide for control of whiteflies (silver leaf whitefly, sweet potato whitefly and greenhouse whitefly) on greenhouse ornamentals and greenhouse vegetables (tomato, cucumber and pepper) by foliar application. Pyriproxyfen is an insect growth regulator and is classified as a juvenile hormone mimic. It interferes with normal insect development and reproduction.

❖ Health Considerations

♦ Can Approved Uses of Pyriproxyfen Affect Human Health?

Pyriproxyfen is unlikely to affect your health when used according to label directions.

Potential exposure to pyriproxyfen may occur through diet (food alone) or when handling and applying the product. There is limited potential for pyriproxyfen to migrate to drinking water sources through the greenhouse uses. When assessing health risks, two key factors are considered: the levels where no health effects occur, and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g., children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pyriproxyfen products are used according to the label directions.

The active ingredient pyriproxyfen caused slight health effects via the inhalation route in animals; consequently, the statement "Caution—Poison" is required on the label. The end-use product Distance caused mild eye and dermal irritation in animals. Because of these effects, the statement "Caution—Skin and Eye Irritant" is required on the label. Pyriproxyfen did not cause cancer in animals and was not genotoxic. There was no indication that pyriproxyfen caused damage to the nervous system or affected

reproduction. There was also no indication that the fetus was more sensitive to pyriproxyfen than the adult animal. The first signs of health effects in animals given daily doses of pyriproxyfen over long periods of time were effects on the liver and kidneys. The risk assessment was conducted to ensure that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

♦ **Residues in Water and Food**

Dietary risks from food and water are not of concern.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Dietary intake estimates (food alone) revealed that children, adults and seniors will typically consume less than 14.7% of the acceptable daily intake for pyriproxyfen. Infants, the subpopulation that would ingest the most pyriproxyfen relative to body weight, are expected to eat less than 6.1% of the acceptable daily intake. The dietary intake estimate for females of childbearing age (13 to 50 years old) was about 2.5% of the reference dose, which is not a health concern. Based on these estimates, the chronic dietary risk from pyriproxyfen is not a concern for all population subgroups.

Animal studies revealed no acute health effects. Consequently, a single dose of pyriproxyfen is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for the *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Greenhouse residue trials conducted throughout Europe (Italy, France, Spain and Greece) using an end-use product containing pyriproxyfen on greenhouse cucumber, pepper and tomato were sufficient to propose MRLs for cucumbers, bell peppers and tomatoes. The specified MRLs for pyriproxyfen can be found in PRDD2006–04, *Proposed Registration Decision—Pyriproxyfen*.

♦ Occupational Risks From Handling Distance

Occupational risks are not of concern when Distance is used according to proposed label directions, which include protective measures

Farmers and pesticide applicators mixing, loading or applying Distance as well as field workers re-entering freshly treated greenhouses, can come in direct contact with pyriproxyfen on the skin or through inhalation of spray mists. Therefore, the label will specify that anyone mixing, loading or applying Distance must wear coveralls or a long-sleeved shirt and long pants, rubber boots, goggles, gloves (rubber, PVC, neoprene or nitrile) and a hat. Based on these mitigation measures and taking into consideration that occupational exposure is expected to be brief as this insecticide is applied up to twice every six months, risk to farmers, applicators or workers is not a concern.

For bystanders, exposure is expected to be much less than that of field workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

❖ Environmental Considerations

♦ What Happens When Pyriproxyfen is Introduced Into the Environment?

Pyriproxyfen is used in greenhouses; therefore, there will be minimal exposure to wild mammals, birds, earthworms, fish, crustaceans, amphibians, algae and aquatic vascular plants. Pyriproxyfen is harmful to beneficial organisms such as predatory and parasitoid insects.

Pyriproxyfen is non-persistent in soil. No major breakdown products are formed in soil. Pyriproxyfen is not expected to leach through the soil profile beyond 30 cm; therefore, it is not expected to enter groundwater. Furthermore, due to its low volatility, pyriproxyfen is not expected to enter the atmosphere.

Pyriproxyfen presents a minimal risk to wild mammals, birds, earthworms, fish, crustaceans, amphibians, algae and aquatic vascular plants when used in a greenhouse. In order to reduce the harmful effects of pyriproxyfen to beneficial insects during application, label instructions are required.

❖ Value Considerations

♦ What Is the Value of Pyriproxyfen?

Pyriproxyfen is an insecticide that controls whiteflies on greenhouse ornamentals and greenhouse vegetables (tomatoes, cucumbers and peppers).

Foliar application of pyriproxyfen controls whiteflies on greenhouse ornamentals and greenhouse vegetables (tomatoes, cucumbers, and peppers). It can be integrated with other chemical and cultural control practices and is compatible with current management practices as well as conventional crop production systems. Growers are familiar with monitoring techniques to determine if and when applications are needed.

Pyriproxyfen is a potential alternative to other classes of insecticides currently registered for control of whiteflies on greenhouse ornamentals and greenhouse vegetables (tomatoes, cucumbers and peppers). Alternative chemistries are needed for use against whiteflies in the greenhouse in order to delay the development of resistance.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures of the Distance label addressing the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

- **Environment**

This following precautionary statement is included on the product label: "Pyriproxyfen should not be applied during peak activity periods of beneficial insects."

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision Document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Requesting a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[5] As per subsection 35(1) of the *Pest Control Products Act*

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PMRA 687088 Magnitude of the Residues of Pyriproxyfen in/on Apples and Apple Processing Fractions. Valent U.S.A. Corporation. Valent Study No. V-95-11119. Study report date: 11-June-1997. Valent Report No. 9700292. pp. 317. DACO 7.4.1. Volume 2.

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PMRA 884509 Magnitude of the Residues of Pyriproxyfen in/on Apples and Apple Processing Fractions. Valent U.S.A. Corporation. Valent Study No. V-95-11119. Study report date: 11-June-1997. Valent Report No. 9700292. pp. 248. DACO 7.4.1. Volume 5.

PMRA 884511 Magnitude of the Residues of Pyriproxyfen in/on Apples and Apple Processing Fractions. Valent U.S.A. Corporation. Valent Study No. V-95-11119. Study report date: 11-June-1997. Valent Report No. 9700292. pp. 208. DACO 7.4.1. Volume 6.

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PMRA 687105 Magnitude of the Residue of Pyriproxyfen in Greenhouse Cucumber Raw Agricultural Commodity- Southern France and Italy 2000. European Agricultural Services & Dr. Specht & Partner. Study No. EA000123 & SUM-0019. Study report date: 26-January-2001. Valent & Sumitomo Report No. NNR-0074. pp. 145. DACO 7.4.1.

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PMRA 687097 Magnitude of the Reside of Pyriproxyfen in Greenhouse Tomato Raw Agricultural Commodity- Spain 1999. European Agricultural Services & Dr. Specht & Partner. Study No. EA990151 & SUM-9938. Study report date: 4-September-2000. Valent & Kenogard S.A. Study No. 200100263 & NNR-0085. pp. 123. DACO 7.4.1.

PMRA 687093 Magnitude of the Residue of Pyriproxyfen in Greenhouse Tomato Raw Agricultural Commodity and Processed Fractions- Spain 2000. European Agricultural Services & Viti R & D & Dr. Specht & Partner. Study No. EA000140 & TOM 0005 EUR & SUM-0028. Study report date: 26-January-2001. Valent & Kenogard & Masso S.A. Report No. 200100265. pp. 188. DACO 7.4.1.

PMRA 687094 Magnitude of the Residue of Pyriproxyfen in Greenhouse Tomato Raw Agricultural Commodity and Processed Fractions- Greece 2000. European Agricultural Services & Viti R & D & Dr. Specht & Partner. Study No. EA000138 & Tom 0004 EUR & SUM-0026. Study Report date: 26-January-2001. Valent & Hallafarm S.A. Report No. 200100264. pp. 183. DACO 7.4.1.

PMRA 687091 Magnitude of the Residues of Pyriproxyfen and its Degradates in Tomatoes. Valent U.S.A. Corporation. Valent Study No. VP-11460. Study report date: 22-April-1998. pp. 303. DACO 7.4.1. Volume 1.

PMRA 884761 Magnitude of the Residues of Pyriproxyfen and its Degradates in Tomatoes. Valent U.S.A. Corporation. Valent Study No. VP-11460. Study report date: 22-April-1998. pp. 282. DACO 7.4.1. Volume 2.

PMRA 884763 Magnitude of the Residues of Pyriproxyfen and its Degradates in Tomatoes. Valent U.S.A. Corporation. Valent Study No. VP-11460. Study report date: 22-April-1998. pp. 219. DACO 7.4.1. Volume 3.

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PMRA 687109 Knack™ Insect Growth Regulator. Magnitude of the Residue of Pyriproxyfen in Cotton Raw Agricultural and Processed Commodities-Five 1995 Field Trials. Valent U.S.A. Corporation. Study No. VP-11117. Study report date: 11-January-1996. Valent Report No. 9600037. pp. 255. DACO 7.4.1.

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5.0–6.0 Impact on the Environment

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PMRA 621892 Artificial Sunlight Photodegradation of 14C-Pyriproxyfen On Soil Hazleton Laboratories America, Inc. Study No. HLA 6311-126, Study report date: 18-October-1995. pp. 202. DACO: 8.2.3.3.1.

PMRA 899326 Hydrolysis of S-31183 in buffered aqueous solutions, Sumitomo Chemical Co. Ltd. Study No. HYD89004, Study report date: 15-December-1989. pp. 61. DACO: 8.2.3.2.

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PMRA 900518 Review of 161-1 Study and 164-1 Protocol of Pyriproxyfen in Support of Registration. EPA DER, 423432-01, 02. 16 August 1993. Valent Biosciences Corporation, N/S. pp. 28. DACO: 8.6.

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7.0 Value

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PMRA 687141 Market Support - Compare to Competition Using Lower Rates (SWF-99-2). DACO 10.2.3.3.

PMRA 687142 Control of Whitefly on Poinsettia in Commercial Greenhouses (SWF-01-3) DACO 10.2.3.3.

PMRA 687143 Evaluate Persistence of Whitefly and Fungus Gnat Control in Ornamentals (SWF-99-4). 10.2.3.3.

PMRA 687144 Evaluate Translaminar Movement in Ornamental Plants (SWF-99-5). DACO 10.2.3.3.

PMRA 687145 Translaminar Activity Against Silverleaf Whitefly in Ornamentals (SWF-00-6) DACO 10.2.3.

PMRA 687146 Evaluate Translaminar Movement in Ornamental Plants (SWF-99-7). DACO 10.2.3.3.

B. Additional Information Considered

i) Published Information

2.0 Methods of Analysis

None used

3.0 Impact on Human and Animal Health

None used

4.0 Residues

None used

5.0–6.0 Impact on the Environment

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7.0 Value

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ii) **List of Unpublished Information Considered**

2.0 Methods of Analysis

None used

3.0 Impact on Human and Animal Health

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4.0 Residues

None used

5.0–6.0 Impact on the Environment

None used

7.0 Value

None used